

§ 493.559

not to be in compliance with requirements equivalent to CLIA requirements.

(6) Submit for Medicare and Medicaid payment purposes, a list of the specialties and subspecialties of tests performed by each laboratory.

(7) Submit a written presentation that demonstrates the agency's ability to furnish CMS with electronic data in compatible code, including the cross-walk specified in § 493.553(a)(1).

(8) Submit a statement acknowledging that the State will notify CMS through electronic transmission of the following:

(i) Any laboratory that has had its licensure or approval revoked or withdrawn or has been in any way sanctioned by the State within 30 days of taking the action.

(ii) Changes in licensure or inspection requirements.

(iii) Changes in specialties or subspecialties under which any licensed laboratory in the State performs testing.

(9) Provide information for the review of the State's enforcement procedures for laboratories found to be out of compliance with the State's requirements.

(10) Submit information that demonstrates the ability of the State to provide CMS with the following:

(i) Electronic data and reports in compatible code with the adverse or corrective actions resulting from PT results that constitute unsuccessful participation in PT programs.

(ii) Other data that CMS determines are necessary for validation and assessment of the State's inspection process requirements.

(11) Agree to provide CMS with written notification of any changes in its licensure/approval and inspection requirements.

(12) Agree to disclose any laboratory's PT results in accordance with a State's confidentiality requirements.

(13) Agree to take the appropriate enforcement action against laboratories found by CMS not to be in compliance with requirements comparable to condition-level requirements and report these enforcement actions to CMS.

(14) If approved, reapply to CMS every 2 years to renew its exempt sta-

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tus and to renew its agreement to pay the cost of the CMS-administered validation program in that State.

§ 493.559 Publication of approval of deeming authority or CLIA exemption.

(a) *Notice of deeming authority or exemption.* CMS publishes a notice in the FEDERAL REGISTER when it grants deeming authority to an accreditation organization or exemption to a State licensure program.

(b) *Contents of notice.* The notice includes the following:

(1) The name of the accreditation organization or State licensure program.

(2) For an accreditation organization:

(i) The specific specialty or subspecialty areas for which it is granted deeming authority.

(ii) A description of how the accreditation organization provides reasonable assurance to CMS that a laboratory accredited by the organization meets CLIA requirements equivalent to those in this part and would meet CLIA requirements if the laboratory had not been granted deemed status, but had been inspected against condition-level requirements.

(3) For a State licensure program, a description of how the laboratory requirements of the State are equal to, or more stringent than, those specified in this part.

(4) The basis for granting deeming authority or exemption.

(5) The term of approval, not to exceed 6 years.

§ 493.561 Denial of application or re-application.

(a) *Reconsideration of denial.* (1) If CMS denies a request for approval, an accreditation organization or State licensure program may request, within 60 days of the notification of denial, that CMS reconsider its original application or application for renewal, in accordance with part 488, subpart D.

(2) If the accreditation organization or State licensure program requests a reconsideration of CMS's determination to deny its request for approval or reapproval, it may not submit a new application until CMS issues a final reconsideration determination.

(b) *Resubmittal of a request for approval—accreditation organization.* An accreditation organization may resubmit a request for approval if a final reconsideration determination is not pending and the accreditation program meets the following conditions:

(1) It has revised its accreditation program to address the rationale for denial of its previous request.

(2) It demonstrates that it can provide reasonable assurance that its accredited facilities meet condition-level requirements.

(3) It resubmits the application in its entirety.

(c) *Resubmittal of request for approval—State licensure program.* The State licensure program may resubmit a request for approval if a final reconsideration determination is not pending and it has taken the necessary action to address the rationale for any previous denial.

§ 493.563 Validation inspections—Basis and focus.

(a) *Basis for validation inspection—(1) Laboratory with a certificate of accreditation.* (i) CMS or a CMS agent may conduct an inspection of an accredited laboratory that has been issued a certificate of accreditation on a representative sample basis or in response to a substantial allegation of noncompliance.

(ii) CMS uses the results of these inspections to validate the accreditation organization's accreditation process.

(2) *Laboratory in a State with an approved State licensure program.* (i) CMS or a CMS agent may conduct an inspection of any laboratory in a State with an approved State licensure program on a representative sample basis or in response to a substantial allegation of noncompliance.

(ii) The results of these inspections are used to validate the appropriateness of the exemption of that State's licensed or approved laboratories from CLIA program requirements.

(b) *Validation inspection conducted on a representative sample basis.* (1) If CMS or a CMS agent conducts a validation inspection on a representative sample basis, the inspection is comprehensive, addressing all condition-level require-

ments, or it may be focused on a specific condition-level requirement.

(2) The number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of the accreditation organization or State.

(c) *Validation inspection conducted in response to a substantial allegation of noncompliance.* (1) If CMS or a CMS agent conducts a validation inspection in response to a substantial allegation of noncompliance, the inspection focuses on any condition-level requirement that CMS determines to be related to the allegation.

(2) If CMS or a CMS agent substantiates a deficiency and determines that the laboratory is out of compliance with any condition-level requirement, CMS or a CMS agent conducts a full CLIA inspection.

(d) *Inspection of operations and offices.* As part of the validation review process, CMS may conduct an onsite inspection of the operations and offices to verify the following:

(1) The accreditation organization's representations and to assess the accreditation organization's compliance with its own policies and procedures.

(2) The State's representations and to assess the State's compliance with its own policies and procedures, including verification of State enforcement actions taken on the basis of validation inspections performed by CMS or a CMS agent.

(e) *Onsite inspection of an accreditation organization.* An onsite inspection of an accreditation organization may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the accreditation process.

(3) Evaluation of accreditation inspection results and the accreditation decision-making process.

(4) Interviews with the accreditation organization's staff.

(f) *Onsite inspection of a State licensure program.* An onsite inspection of a State licensure program office may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the licensure or approval process.